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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/991,610	11/09/2001	Eric C. Hannah	042390.P13119	7624

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EXAMINER

TRAN, MY CHAU T

ART UNIT	PAPER NUMBER
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1639

DATE MAILED: 10/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/991,610

Applicant(s)

HANNAH, ERIC C.

Examiner

My-Chau T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 July 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-18,31-40 and 42-48 is/are pending in the application.
- 4a) Of the above claim(s) 40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 14-18,31-39 and 42-48 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

1. Applicant's amendment filed 7/28/03 in Paper No. 11 is acknowledged and entered.

Claims 19-20, and 41 are canceled by the amendment. Claims 14, 18, 32, 42-43 are amended by the amendment.

2. Claims 14-18, 31-40, and 42-48 are pending.

Election/Restrictions

3. Claim 40 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 9.

Withdrawn Rejections

4. The previous objection for the disclosure, because it contains an embedded hyperlink and/or other form of browser-executable code, has been withdrawn in view of applicant's amendments of the disclosure by deleting the embedded hyperlink and/or other form of browser-executable code.

5. The previous rejections 35 USC 112, first paragraph, for claims 14-20, 33-36, 39, and 41-48 have been withdrawn in view of applicant's amendments of claim 14 and cancellation of claims 19-20, and 41. Additionally, applicant traversal of this rejection is noted.

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6. The previous rejections 35 USC 112, second paragraph, for claims 14-20, 31-39, and 41-48 have been withdrawn in view of applicant's amendments of claim 14 and cancellation of claims 19-20, and 41.

7. Claims 14-18, 31-39, and 42-48 are treated on the merit in this Office Action.

Maintained Rejections

8. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 102

9. Claims 14-15, 19-20, 33, 41-42, and 45-48 are rejected under 35 U.S.C. 102(b) as being anticipated by Massey et al. (US Patent 5,866,434).

Massey et al. disclose an assay method (method of identifying a probes or analytes) using functionalized carbon nanotubes (col. 40. lines 12-14). The assay methods include a DNA probe assay using carbon nanotubes (col. 40, lines 41-57). The method comprises 'the steps of: (a) forming a composition containing, (i) said sample, (ii) an assay-performance-substance which contains a component linked to a label compound capable of being induced to luminesce, and (iii) a plurality of functionalized graphitic nanotubes bound to an assay-performance-substance (refers to step (a) of claim 14); (b) incubating said composition to form a complex which includes said functionalized graphitic nanotube and said label compound; (c) collecting said complex in a measurement zone; (d) inducing the label compound in said complex to luminesce

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by surface selective excitation (refers to step (b)), and (e) measuring the emitted luminescence to measure the presence of the analyte of interest in the sample (refers to step (c))' (col. 13, lines 9-31). Biotinylated ssDNA (the "analyte") bound to the avidin fibrils and was detected by the ECL of a complementary single stranded oligonucleotide, which had been labeled (refers to claims 19-20 and 33) (col. 40, lines 47-57). The methods of the invention can be carried out in a static or flow-through mode (refers to claims 45-48) (col. 21, lines 65-67). The apparatus comprise of a light detection/measurement device and a pump to provide for fluid transport to, through and from cell (microchannel) (col. 22, lines 6-19). Therefore, the method of Massey et al. anticipates the presently claimed invention.

Response to Arguments

10. Applicant's argument directed to the above rejection under 35 USC 102(b) as being anticipated by Massey et al. (US Patent 5,866,434) for claims 14-15, 19-20, 33, 41-42, and 45-48 was considered but they are not persuasive for the following reasons.

Applicant contends that the method of Massey et al. does not anticipate the presently claimed invention because Massey et al. do not described that the emission spectrum is from the nanotube itself but rather from a label attached to the nanotube (e.g. a luminescent label). Thus the method of Massey et al. does not anticipate the presently claimed invention.

Applicant's arguments are not convincing since the method of Massey et al. does anticipate the presently claimed method. The carbon nanotube of Massey et al. is not just a support but rather it induces the luminescent label to produce an emission spectrum (col. 6, lines 28-31; col. 7, lines 44-46) (e.g. "*exciting the nanotubes and detecting the emission spectra of the excited nanotubes*"). Additionally, the specification disclosure described labeling the probe with

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a “label” (see pg. 18, paragraphs [0067] to [0069]) wherein the “label” is define as “*any atom, molecule, compound or composition that can be use to identify an analyte to which the label is attached*” (see pg. 3, paragraph [0016]). The examples of the “label” include chemiluminescent label (see pg. 4, paragraph [0016]). Thus the detection of the emission spectrum is from the label attached to the nanotube would not excluded base on the claimed limitation of “*detecting the emission spectra of the excited nanotubes*”. Therefore, the method of Massey et al. does anticipate the presently claimed method.

Claim Rejections - 35 USC § 103

11. Claims 14-20 and 31-48 are rejected under 35 U.S.C. 103(a) as being unpatentable over Massey et al. (US Patent 5,866,434) and Wohlstadter et al. (US Patent 6,140,045).

Massey et al. disclose an assay method (method of identifying a probes or analytes) using functionalized carbon nanotubes (col. 40. lines 12-14). The assay methods include a DNA probe assay using carbon nanotubes (col. 40, lines 41-57). The method comprises ‘the steps of: (a) forming a composition containing, (i) said sample, (ii) an assay-performance-substance which contains a component linked to a label compound capable of being induced to luminesce, and (iii) a plurality of functionalized graphitic nanotubes bound to an assay-performance-substance (refers to step (a) of claim 14); (b) incubating said composition to form a complex which includes said functionalized graphitic nanotube and said label compound; (c) collecting said complex in a measurement zone; (d) inducing the label compound in said complex to luminesce by surface selective excitation (refers to step (b)), and (e) measuring the emitted luminescence to measure the presence of the analyte of interest in the sample (refers to step (c))’ (col. 13, lines 9-

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31). Biotinylated ssDNA (the "analyte") bound to the avidin fibrils and was detected by the ECL of a complementary single stranded oligonucleotide, which had been labeled (refers to claim 19-20). The methods of the invention can be carried out in a static or flow-through mode (refers to claims 45-48) (col. 21, lines 65-67). The apparatus comprise of a light detection/measurement device and a pump to provide for fluid transport to, through and from cell (microchannel) (col. 22, lines 6-19).

The method of Massey et al. does not expressly disclose that the method comprises identifying one or more peaks in the optical emission spectrum of each nanotube.

Wohlstadter et al. disclose an assay method using carbon nanotubes (col. 12, lines 42-45). The assay method comprise of '(a) contacting one or more of a plurality of discrete binding domains, said plurality of binding domains (i) being immobilized on a surface of one or more supports, and (ii) being spatially aligned with and in proximity to a plurality of electrode and counter electrode pairs, in which said contacting is with a sample comprising molecules linked to an electrochemiluminescent label; (b) bringing an electrode and counter electrode into proximity to said one or more of a plurality of binding domains; (c) applying a voltage waveform effective to trigger electrochemiluminescence at said one or more of a plurality of binding domains; and (d) detecting or measuring electrochemiluminescence' (col. 9, lines 61-67 to col. 10, lines 1-6). The assay includes DNA binding assay (col. 20, lines 51-67 to col. 21, lines 1-19; col. 55, lines 51-67). The method of detection includes 'detecting of sequential emissions or may be plural to detect and spatially resolve simultaneous emissions at single or multiple wavelengths of emitted light' (col. 26, lines 1-17).

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to include the method step of identifying one or more peaks in the optical emission spectrum of each nanotube as taught by Wohlstadter et al. in the method of Massey et al. One of ordinary skill in the art would have been motivated to include the method step of identifying one or more peaks in the optical emission spectrum of each nanotube in the method of Massey et al. for the advantage of providing a rapidly and efficiently method to collect large amounts of data that can be stored, e.g., in the form of a database consisting of a collection of clinical or research information. The data collected may also be used for rapid forensic or personal identification. For example, the use of a plurality of nucleic acid probes when exposed to a human DNA sample can be used for a signature DNA fingerprint that can readily be used to identify clinical or research samples (Wohlstadter: col. 27, lines 35-43). Since both Massey et al. and Wohlstadter et al. disclose the assay method using carbon nanotubes (Massey: col. 40. lines 12-14; Wohlstadter: col. 12, lines 42-45).

Response to Arguments

12. Applicant's argument directed to the above rejection under 35 USC 103(a) as being unpatentable over Massey et al. (US Patent 5,866,434) and Wohlstadter et al. (US Patent 6,140,045) for claims 14-20 and 31-48 were considered but they are not persuasive for the following reasons.

Applicant alleges that the combination of Massey et al. and Wohlstadter et al. is not obvious over the presently claimed invention because both Massey et al. and Wohlstadter et al. do not described that the emission spectrum is from the nanotube itself but rather from a label

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attached to the nanotube (e.g. a luminescent label). Thus the combination of Massey et al. and Wohlstadter et al. is not obvious over the presently claimed invention.

Applicant's arguments are not convincing since the combination of Massey et al. and Wohlstadter et al. is obvious over the presently claimed method. The carbon nanotube of Massey et al. is not just a support but rather it induces the luminescent label to produce an emission spectrum (col. 6, lines 28-31; col. 7, lines 44-46) (e.g. "*exciting the nanotubes and detecting the emission spectra of the excited nanotubes*"). Additionally, the specification disclosure described labeling the probe with a "label" (see pg. 18, paragraphs [0067] to [0069]) wherein the "label" is define as "*any atom, molecule, compound or composition that can be use to identify an analyte to which the label is attached*" (see pg. 3, paragraph [0016]). The examples of the "label" include chemiluminescent label (see pg. 4, paragraph [0016]). Thus the detection of the emission spectrum is from the label attached to the nanotube would not excluded base on the claimed limitation of "*detecting the emission spectra of the excited nanotubes*". Therefore, the combination of Massey et al. and Wohlstadter et al. is not obvious over the presently claimed method.

Conclusion

13. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to My-Chau T. Tran whose telephone number is 703-305-6999. The examiner is on Increased Flex Schedule and can normally be reached on Monday: 8:00-2:30; Tuesday-Thursday: 7:30-5:00; Friday: 8:00-3:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Andrew J. Wang can be reached on 703-306-3217. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1123.

mct
October 14, 2003


PADMASHRI PONNALURI
PRIMARY EXAMINER